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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/321,179 10/11/94 CARNEY W 40441CZJPWNF

JOHN P. WHITE  
COOPER AND DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK NY 10112

HM22/1011

EXAMINER

HUNT, J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

10/11/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>08/321,179</b>	Applicant(s) <b>Carney et al.</b>
Examiner <b>Jennifer Hunt</b>	Art Unit <b>1642</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 5, 1996

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-18 is/are pending in the application.

4a) Of the above, claim(s) 3-18 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1 and 2 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20)  Other: \_\_\_\_\_

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***Response to Amendment***

Claims 1-18 are pending in the application. Claims 3-18 have been withdrawn from consideration as being drawn to a non-elected invention. Upon further consideration, the indicated allowability of claims 1-2 is withdrawn in view of the new rejections set forth below.

The examiner and art unit for this application have changed. Please address future correspondence to Jennifer Hunt, Art Unit 1642.

***Claim Objections***

1. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites an inherent property of the claimed p100 (capable of being detected in an immunoblot format...), which fails to further limit the structure or physical properties of the instantly claimed product.

***Claim Rejections - 35 U.S.C. § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. The term "corresponds substantially" in claims 1 and 2 is a relative term which renders the claim indefinite. The term "corresponds substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The specification discloses that "corresponds substantially provides conservative additions, deletions and/or substitutions." (See page 11, lines 1-2 of the original disclosure). Further applicant argues that one of skill in the art recognizes what extent of additions, deletions, and substitutions would be considered conservative, and further cites a reference which, according to applicant "suggests candidates for conservative substitutions". Applicant's arguments filed 4-5-1996 have been fully considered but they are not persuasive.

Initially, it is noted that at page 11 of the specification where "corresponds substantially" is described, the term "conservative" only modifies "additions"; the terms "deletions and/or substitutions" are not modified by "conservative" and thus encompass any deletion and/or substitution. Further, it is still not clear what extent of sequence variation could be tolerated and still meet the limitations of the claims. Even if the term "conservative" described any of the possible sequence modifications, "conservative" is a relative term who's metes and bounds are unclear. Further, the reference cited by applicant is a mere teaching reference which refers to the general structure of amino acids, and does not teach or suggest what would be considered a conservative amino acid sequence modification.

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are broadly drawn to any "p100" which is a neu related protein having a molecular weight from about 97,000 daltons to about 115 daltons which corresponds substantially to the extracellular domain of the human neu gene product, and which is detectable in biological fluid. Thus the claims encompass any compound having a molecular weight in the broad range of about 97,000 daltons to about 115 daltons and which has any number of additions, deletion and/or substitutions in the compound's structure.

Thus the claims are drawn to a large genus of molecules. In the case of small identified amino acid residues claimed with open language, the genus of the polypeptides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of one species, the human neu polypeptide. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polypeptides at the time the instant application was filed.

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*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

Applicant is referred to the guidelines for 112, first paragraph, published in the Official gazette and also available on [www.uspto.gov](http://www.uspto.gov).

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***Claim Rejections - 35 U.S.C. § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Prior to setting forth the rejections, it is noted that the effective filing date of the instant claims is determined to be 9/29/1989. Prior to this date, none of the CIP applications cited for priority disclosed the full scope of the instant claims. Specifically, limitations and terminology including "p100" and "molecular weight from about 97,000 daltons to 115, 000 daltons" were not disclosed.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernards et al., PNAS, Vol. 84, pages 6854-6858, October 1987.

Bernards et al. teaches a human *neu* related protein (rat *neu*) comprising the extracellular domain of the *neu* gene product, and which has a molecular weight of about 97,000 daltons to about 115 daltons (100 daltons). (see for example, page 6855 and figure 2). That the protein is detectable in biological fluid is an inherent property of the composition.

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8. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Hudziak et al., US Patent 6,015,567.

Hudziak et al., US Patent 6,015,567 teaches a substantially purified human *neu* related protein comprising the extracellular domain of a *neu* related gene product and which has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, column 1, lines 15-20, column 6, line 55-column 7, line 6, and figure 12 (including description)). That the protein is detectable in biological fluid is an inherent property of the composition.

9. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Ring, US Patent 6,054,561.

Ring, US Patent 6,054,561 teaches a substantially purified human *neu* related protein comprising the extracellular domain of a *neu* related gene product and which has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, abstract, column 5, lines 24-40, and column 27, lines 1-40). That the protein is detectable in biological fluid is an inherent property of the composition.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[anthony.caputa@uspto.gov\]](mailto:anthony.caputa@uspto.gov).

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

October 9, 2001

10/9/01  
JENNIFER HUNT  
PATENT EXAMINER  
TECHNOLOGY CENTER 1600